In the United States Court of Federal Claims

No. 95-356-V

(Filed: September 15, 1999)

* *

THOMAS WALERYSZAK and JUDY WALERYSZAK Regarding the Death of JOSHUA THOMAS WALERYSZAK,

Plaintiff,

v.

SECRETARY OF THE DEPARTMENT HEALTH AND HUMAN SERVICES,

Defendant.

* *

National Childhood Vaccine Act, 42 U.S.C. § 300aa et seq. (1994); Standard of Review; Burden of Proof.

Allan W. Munro, Seattle, Washington, for petitioners.

Caroline Gosse Elmendorf and Gerard W. Fischer, United States Department of Justice, Washington, D.C., for respondent, with whom were ***Acting Assistant Attorney General David W. Ogden, Director Helene M. Goldberg,*** and ***Deputy Director John Lodge Euler***.

ORDER

TIDWELL*, Senior Judge*:

This case is before the court on petitioners' motion for review of the March 9, 1999 decision of Special Master Laura D. Millman denying compensation under the National Child Vaccine Injury Act[(1)] ("Vaccine Act"), 42 U.S.C. § 300aa et seq. (1994). *See Waleryszak v. Secretary of Secretary of HHS*, No. 95-356-V, 1999 WL 199054 (Fed. Cl. Sp. Mstr. March 9, 1999) (dismissal order). Petitioners claim the special master committed reversible error and was arbitrary and capricious in denying their original petition for a compensation award pursuant to the Vaccine Act. For the reasons set forth below, the court denies petitioners' motion for review and affirms the special master's decision.

FACTS

On behalf of Joshua Thomas Waleryszak ("Joshua"), petitioners filed a petition on May 22, 1995 for compensation under the National Childhood Vaccine Injury Act. Joshua was born on March 24, 1981. From the beginning, it was apparent that Joshua was developmentally delayed, manifested by a short attention span and high distractibility. In 1987, Joshua began to have seizures and show signs of developmental regression. No longer was Joshua able to walk or sit up independently. He was diagnosed as having static encephalopathy of unknown etiology, and Lennox-Gastaut syndrome with tonic, atonic, myoclonic and generalized tonic/clonic seizures. Further, Joshua had developed a history of respiratory problems, namely a recurring incidence of aspiration pneumonia.

In 1993, Joshua had been scheduled to have oral surgery on August 19th to remove his baby teeth in order to improve his ability to swallow. On August 16, 1993, Joshua had reportedly undergone continuous seizure activity, and on August 17th, a decision to delay his surgery was made after his pre-surgery examination found he was suffering from 'loud rhonchi' (i.e., wheezing caused by mucus build up), possibly due to a slow recovery from pneumonia which he had been previously hospitalized for earlier that same month. Yet on August 20th, his health had recuperated to where he was more alert, active and atoxic; further, his global status and electrolytes had improved. Consequently, on August 20, 1993, Joshua was given a mumps, measles and rubella (hereinafter "MMR") vaccination and a hepatitis B virus (hereinafter "HBV") vaccination.

Afterwards, Joshua's parents brought him home where they personally took watch of his care. On August 21, 1993, Joshua began having increased seizures and was admitted to Group Health Hospital after falling into a deep sleep and becoming non-responsive to stimuli. He was then transferred to Children's Hospital on August 22, 1993, after being diagnosed with cerebral edema and acute increased intracranial hypertension. Joshua's condition worsened as he remained in a catatonic state with his breathing becoming increasingly laborious. Despite a faculty of specialists attending to Joshua, he was declared brain dead on August 23, 1999. His parents refused to have Joshua undergo an autopsy after being consulted by his doctor. The cause of death entered on Joshua's death certificate was cerebral edema, due to probable infection (encephalitis). Listed as a significant factor contributing to his death was progressive encephalopathy.

Several virology tests were conducted prior to the harvesting of Joshua's organs. These tests concluded that there was no reaction for the respiratory syncytial virus, for the influenza A or B viruses, or for the parainfluenza viruses. In the final report, these tests also concluded that no viruses had been isolated.

On May 22, 1995, Thomas and Judy Waleryszak, filed a petition for compensation under the Vaccine Act on behalf of their son. The petition, as amended on February 6, 1998, alleged that Joshua's death was caused by the HBV and MMR vaccinations administered to him on August 20, 1993. Petitioners have since conceded that no Table Injury may be established. *See* discussion *infra* Part III of Discussion. After holding a hearing on December 9, 1998, the special master handed down a decision on March 9, 1999 concluding that petitioners failed to present a prima facie case that the MMR and/or HBV vaccinations caused in fact claimant's post-vaccinal illness, and have failed to present a prima facie case of significant aggravations. On April 7, 1999, petitioners filed a Motion for Review to the U.S. Court of Federal Claims to review the special master's decisions.

DISCUSSION

I. Standard of Review.

Pursuant to the Vaccine Act, review by the Court of Federal Claims is limited to (1) upholding the findings of fact and conclusions of law sustaining the decision of the special master; (2) setting aside the special master's finding of fact or conclusion of law "found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" and issuing separate and independent findings and conclusions; or (3) remanding the petition to the special master for further action in accordance with the court's direction. 42 U.S.C. § 300aa-12(e)(2); *see Munn v. Secretary of HHS*, 970 F.2d 863, 869 (Fed. Cir. 1992). Thus, determinations of fact, as disputed in the instant case, are reviewed by this court under the arbitrary and capricious standard. *See Lampe v. Secretary of HHS*, 42 Fed. Cl. 632, 636 (1998); *McCarren v. Secretary of HHS*, 40 Fed. Cl. 142, 146 (1997). This standard is to be narrowly construed, paying great deference to the special master's conclusions of fact. *See McCarren, supra*, 40 Fed. Cl. at 146; *Munn, supra*, 970 F.2d at 870. As a result, decisions made by the special master will only be found to be capricious or arbitrary if the special masterrelied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence . . . or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

See Hines v. Secretary of HHS, 940 F.2d 1518, 1527 (Fed. Cir. 1991) (*quoting Motor Vehicle Mfrs. Ass'n . State Farm Mutl Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)); *see also* Lampe, supra, 42 Fed. Cl. at 637.

II. Recovery Under the Vaccine Act.

Under the Vaccine Act, claimants may petition for compensation under two theories of recovery. First, petitioners may be entitled to a rebuttable presumption that the vaccine in fact caused the injury, harm or illness at issue upon meeting certain criteria. 42 U.S.C. 300aa-13(a)(1)(A); *see Vant Erve v. Secretary of HHS*, 43 Fed. Cl. 338, 342-343 (1999). In order to qualify for this causal presumption, petitioners must first prove the claimant's illness, disability, injury, or condition was listed on the Vaccine Injury Table. 42 U.S.C. § 300aa-11(c)(1)(C)(i). Additionally, a claim for compensation may also be made for significant aggravation of a table injury which seriously deteriorate the claimant's condition. *See Whitecotton v. Secretary of HHS*, 81 F.3d 1099, 1102-03 (Fed. Cir. 1996). Further, under the 1989 Amendments to the Vaccine Act, petitioners must also prove that the claimant's illness, disability, injury, or condition occurred during a specified time period, as enumerated on the Vaccine Injury Table. 42 C.F.R. § 100.3. This presumption may be rebutted upon showing, by a preponderance of the evidence, that the aforementioned affliction was in fact caused by something other than the vaccination. 42 U.S.C. § 300aa-13(a)(1).

The second theory of recovery under the Vaccine Act requires petitioners to prove that the immunization in fact caused the claimant's illness, disability, injury, or condition. 42 U.S.C. 300aa-11(c)(1)(C)(ii). Petitioners must prove this causal link by a preponderance of the evidence, a burden that is not easily established. 42 U.S.C. § 300aa-13(a)(1)(A); *see Shyface v. Secretary of HHS*, 165 F.3d 1344, 1349 (Fed. Cir. 1999). The Federal Circuit has recently resolved a split in its lower courts by embracing the substantial factor analysis, as adopted by the Restatement (Second) of Torts § 431, in determining legal causation. *See Shyface, supra*, 165 F.3d at 1352. Specifically, petitioners must prove, by a preponderance of the evidence, that the vaccinations were "a 'substantial factor' in bringing about the harm, and that the harm would not have occurred but for the action." *Id.* In this effort, petitioners must demonstrate a logical sequence of events, which reasonably support the causal connection, and are corroborated by reputable medical or scientific explication. 42 U.S.C. § 300aa-13(a)(1); *see Grant v. Secretary of HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992) (*citing Hasler v. U.S.*, 718 F.2d 202, 205-206 (6th Cir. 1983)). Consequently, temporal association of the onset of the injury and the vaccination, without more, is not sufficient to prove

legal causation. *See Grant, supra*, 956 F.2d at 1148.

In sum, non-table injuries must be proven, "by a preponderance of the evidence, that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *See Shyface, supra*, 165 F.3d at 1352. If petitioners are able to show, by a preponderance of the evidence, that the vaccine in fact caused claimant's injury, respondent may rebut this showing, by a preponderance of the evidence, that the illness was in fact caused by something other than the vaccination. 42 U.S.C. § 300aa-13(a)(1)(B).

III. Causation in Fact.

In the instant case, petitioners concede that there is no Table injury because the onset of Joshua's symptoms arose less than five days of the HBV and MMR inoculations.[(2)] Therefore, petitioners' sole remaining theory of recovery is causation in fact.[(3)] This case revolves around the parties' expert witnesses and their conclusions about the cause of Joshua's death. Petitioners' expert witness, Dr. Cantwell, contended that Joshua's death was precipitated under two alternative, yet probable, theories of causation. First, Dr. Cantwell believed that Joshua could have developed hypersensitivity vasculitis or cerebral angiitis. In the alternative, Dr. Cantwell hypothesized that Joshua could have had hypoxic encephalopathy caused by either seizures occurring while he was asleep or from aspiration.

The government's expert witness, Dr. Sladky, refuted petitioners' expert's findings. Dr. Sladky testified that Joshua did not suffer from an MMR vaccine related encephalopathy. Instead, Dr. Sladky believed his death was caused by viral encephalitis not the result of either the MMR or the HBV inoculations.

In cases like these, circumstantial evidence is often employed to prove the causal link between immunization and the injury. *See McCumming v. Secretary of HHS*, No. 90-903V, 1992 WL 182190, *11 (Cl. Ct. Spec. Mstr. July 10, 1990); *Torres v. Secretary of HHS*, No. 89-40V, 1990 WL 293396, *5 (Cl. Ct. Spec. Mstr. Aug. 3, 1990). The instant case is no exception. In this vein, both parties utilized expert witnesses, personal testimony, various medical research, as well as medical reports documented by the medical staff attending to Joshua. The special master made her decision based on the weight of the evidence presented. In the end, the special master determined that petitioners' expert witness was not very credible, and petitioners failed to prove their burden of showing, by a preponderance of the evidence, that but-for the vaccinations, their son would not have suffered the resulting fatality.

Issues of credibility are left within the sole dominion of the trier of fact. *See Giles v. Secretary of HHS*, 37 Fed. Cl. 525, 540 (1997) (*citing Inwood Lab., Inc. v. Ives Lab., Inc.*, 456 U.S. 844, 856 (1982)), *aff'd by* 168 F.3d 1316 (Fed. Cir. 1998). In vaccine cases, the special master, as trier of fact, has the arduous task of making an independent review of the record as a whole and determining the outcome based on the weight of the evidence presented. In arriving at these conclusions, the special master has the discretion to deem some evidence more credible than other evidence, thus giving greater weight to that evidence. *Vant Erve v. Secretary of HHS*, 43 Fed. Cl. 338, 344 (1999) (*citing Whitecotton, supra*, 81 F.3d at 1107-08). The consideration of the circumstantial evidence in the instant case, albeit medical in nature and greatly adduced from expert testimony must, however, be reliable and based on a trustworthy source. *See Daubert v. Merrel Dow Pharaceuticals*, 509 U.S. 579, 590 & fn. 9 (1993).

In the case at bar, the special master determined that the testimony of petitioners' expert witness was not reliable. The special master arrived at this conclusion after much deliberation and inspection of the whole record, as indicated by her final decision. Specifically, the special master concluded that Dr. Cantwell, although certainly a fully capable medical doctor and respected pediatrician, was not fitly qualified to testify on matters involving the diagnosing of pediatric neurological dysfunctions. The special master reasonably discerned that Dr. Cantwell's expertise was more suited to managing the care of these patients, as opposed to diagnosing and treating them. The special master reasonably determined that the outcome of this case hinged on petitioners' ability to show, by a preponderance of the evidence, that the vaccinations administered to their son was the factual cause of his death. In this regard, the special master reasonably concluded that an expert witness whose specialty was in diagnosing illnesses, a task inherently demanding the discovery of causal origins of such afflictions, was more useful and reliable than that of an expert whose specialty was in managing such ailments.

Even assuming arguendo, that petitioners' expert witness did have some training and experience in diagnosing neurological diseases, as relevant to the instant case, the special master did not abuse her discretion in concluding that respondent's expert witness was more reliable than petitioners' expert witness and, therefore, reasonably applied greater weight to the former's testimony. *See Bradley v. Secretary of HHS*, 991 F.2d 1570, 1575 (Fed. Cir. 1993) (court found conclusions of special master appropriate relating to credibility issues of an expert witness who had considered record in making opinion). As the record clearly shows, Dr. Cantwell's predominant experience lay in pediatrics and developmental neurology, focusing on managing the care of developmentally delayed children. In his early career, Dr. Cantwell did complete a fellowship in community pediatrics at Johns Hopkins Hospital in Baltimore, Maryland. He is also licensed by the Florida State Board of Medicine and has had numerous faculty appointments at various universities teaching pediatrics. Dr. Cantwell's most recent experience lay in the coordination of quality assurance of a managed health care plan. In considering Dr. Cantwell's background and qualifications, his testimony, and the various medical literature from which much of his medical opinion was based upon, the special master clearly was not arbitrary or capricious in rendering her factual conclusions about the credibility of Dr. Cantwell. Although seemingly credible in the area of pediatrics and health care management, the special master did not abuse her discretion in concluding that this expert was not credible when testifying about diagnosing neurological diseases. The special master reasonably determined that Dr. Cantwell lacked the specialized knowledge and experience that would allow him to make an informed and reliable opinion about the cause of Joshua's death. *See Giles, supra*, 37 Fed. Cl. at 540 (court determined that special master was free to accept or reject opinions of medical experts in light of the entire record).

The special master reasonably concluded that respondent's expert witness, Dr. Sladky, could credibly testify after an examination of his experience and expertise in diagnosing pediatric neurological diseases. The record clearly shows that Dr. Sladky has a well established record of diagnosing neurological diseases, has written numerous medical literature on the subject matter, and is a board certified pediatric neurologist. He also serves as the Director of the Division of Pediatric Neurology at the Emory University Medical Center in Atlanta, Georgia. In determining Dr. Cantwell's ability to testify that Joshua's death resulted from the vaccinations, in comparison to Dr. Sladky's qualifications and command of the relevant issues, the special master unquestionably exercised reasonable and fair discretion on the issue of credibility.

Having had no benefits of an autopsy, the special master was constrained to look to Joshua's medical records, the experts, medical literature, and other witnesses to determine whether petitioner could prove causation by a preponderance of the proof. In doing so objectively, the special master further found that petitioners' expert witness's opinion was not based on reputable scientific or medical evidence. The medical literature provided by Dr. Cantwell was unsupportive of his theory of causation. Dr. Cantwell's main proposition, in reliance of his submitted medical literature, was that if HBV or MMR vaccinations could cause various demyelinating diseases, then these inoculations also had the potential of causing death. The problem in this reliance is that none of the submitted medical reports supported his theory. For example, petitioners' expert relied on an article by A. Bretzin, M.D., et als, entitled Acute Posterior Multifocal Placoid Pigment Epitheliopathy After Hepatitis B Vaccine, 113 Arch Opthalmol 297 (March 1995). This article concluded that HBV immunizations may be a risk factor for acute multifocal placoid pigment epitheliopathy, which based its analysis on case studies reporting visual loss of two patients within three days to two weeks after being administered HBV inoculations. The special master was not clearly erroneous in giving little weight to this or any other reports submitted by petitioners and Dr. Cantwell's conclusions in reliance thereon for several reasons. First, the claimant in the instant case lapsed into a coma less then one day after being administered the HBV vaccine. The special master reasonably determined that amount of time transpiring between inoculation and symptoms caused by the vaccination was found to be a significant factor when establishing opinion of causation. Neither this report, nor any other relied upon medical literature submitted by petitioners' expert, advanced any evidence or discourse on HBV or MMR vaccinations symptomatic of a coma one day after inoculation, which led to death two days later. The conclusion reached by the special master that Dr. Cantwell's theory was speculative was not a clearly erroneous error, given the inconclusiveness of these relied upon medical reports. Second, the Bretzin case study is a report involving the optic nerve which implicates retinal vasculitis, not brain vasculitis as relevant to Joshua's case. One of Dr. Cantwell's theories was that because the retina is considered a neural tissue, which could possibly be adversely affected by HBV inoculations, the same vaccinations could also trigger an allergic reaction causing a devastating immune mediated encephalopathy affecting predominantly the cerebral cortex and grey matter of the brain. This connection, nevertheless, was based on the presupposition that the correlation found in the case study was in fact a causal conclusion. This postulation was not, however, based on this or any other reports. Rather, the Bretzin report concludes that there was no definitive causal relationship between the HBV vaccine and any neurologic finding. Thus, one must presuppose this causal link before relying on this report to theorize on the diagnosis of a patient's condition. The special master did have reasonable justification in reaching her conclusion that Dr. Cantwell's theory remained unsupported by the medical literature provided by petitioners.

Petitioners also argue that the special master made erroneous findings about the claimant's medical records. Specifically, the special master determined that hypersensitivity vasculitis and cerebral angiitis, as posited by Dr. Cantwell as being one of the causes of Joshua's death, were not identified in his medical records. The clinical notes taken on August 22, 1993, one day before his death, do mention the possibility of vasculitis or cerebral vasculitis angiitis. However, the position taken by petitioners is misleading, in that these records do not represent a conclusive diagnosis. Rather, both of these alternative diagnoses were mere possibilities, among others, that Joshua's doctors were still contemplating. Neither one was ever found to be the final diagnosis of his doctors. Therefore, the special master did not make an erroneous factual finding that hypersensitivity vasculitis or cerebral angiitis were not conclusively identified as the cause of Joshua's death.

Petitioners additionally assert that Dr. Sladky's opinion, explaining that the fact Joshua's test results had found that no viruses could be isolated was due to the fallibility of such tests, falls in the face of logic. Specifically, Dr. Sladky opines that particular viruses are identified in only 30% of the cases for viral encephalitis, whereas Dr. Cantwell testified to a higher percentage of 40%. Petitioners argue that because multiple testing was done, the percentage that detection of a viral infection would have been found with a higher probability rate. The special master, in accepting Dr. Sladky's testimony as credible in relation to Joshua's medical records, was reasonable in concluding that the tests which Joshua had undergone for viral infection were only accurate about 30% of the time. Assuming arguendo, however, that this finding was not reasonable, this particular issue has no bearing on the case at bar. Respondent's did not bear the burden to prove that claimant's fatality was the result of some factor other than the vaccine until and unless petitioners first proved, by a preponderance of the evidence, that claimant's injuries were the cause of the inoculations. However, the special master reasonably concluded that petitioners never met their burden, so respondent never bore the burden of proving otherwise.

Petitioners further insist that the special master erred in finding that petitioners, as caretakers of claimant, may not have noticed their son having a hypoxic event. As the record indicates, a hypoxic event is characterized by gasping respirations. Petitioners remark that Joshua's cough and swallow reflexes were impaired due to his preexisting condition, thus making it difficult for anyone to notice this event. Joshua's parents were not merely any caretaker though. The record is clear in displaying Joshua's parents as being very caring, concerned and attentive to their son's needs. The special master determined petitioners, given their vigilant and observant nature, would not have missed such an occurrence. This finding was not clearly erroneous given the fact that both parents were home and able to observe Joshua. Further, they had observed their son in this state of troubled breathing on numerous occasions, and it was not an erroneous finding that his parents would have noticed a significant change in Joshua's respiratory behavior. Moreover, such a hypoxic event, as postulated by petitioners, would have to be proven by a preponderance of the evidence. Mere speculation or theorization, without more, is not enough. Therefore, the special master was reasonable in finding that a hypoxic event had not occurred.

Petitioners argue that their burden does not rise to the level of explaining precisely the manner in which the HBV and MMR vaccinations caused Joshua's death, rather they need only prove a sequence of causation which more probably than not led to claimant's death. The court agrees with petitioner's assertion, however, also finds that the special master's decision correctly addressed this argument. The special master determined, in light of petitioners'

evidence, that their explanation of how claimant died was not reliable and could be neither the but-for cause of Joshua's death nor a substantial factor in bringing about his injury. *See Shyface, supra*, 165 F.3d at 1352. The Vaccine Act states that the special master may not make findings "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." 42 U.S.C. § 300a-13(a)(1)(B). As stated previously, the special master did not abuse her discretion in finding that petitioner's expert witness lacked the expertise and experience required to diagnose and treat illnesses in the area of medicine at issue before the court. Further, after a review of the whole record, the court finds that the special master was not arbitrary or capricious in concluding that the medical records did not support petitioners' theory of causation by a preponderance of the evidence. Therefore, the special master was left with petitioners' claims standing alone. The special master had no choice but to deny petitioners' claim.

The court realizes these cases are very painful for the parties involved; indeed Congress believed the issue important enough to permit compensation awards in certain circumstances for those who have been harmed by vaccines. However, in the instant case, petitioners have failed to prove, by a preponderance of the evidence, that the vaccinations at issue in fact caused the plight of the claimant. Lacking a preponderance of proof, as drawn from the record, the court is dutifully required to deny petitioners' Motion For Review.

CONCLUSION

Upon review of Special Master Millman's decision and applicable case law, the court finds that petitioner has failed to demonstrate that denial of their claim was arbitrary, capricious, or otherwise not in accordance with the law. As a result, petitioners' Motion For Review is denied. The court, pursuant to 42 U.S.C. § 300aa-12(e)(2)(A), hereby sustains the special master's March 9, 1999 decision. The Clerk of the Court is directed to enter judgment accordingly.

IT IS SO ORDERED.

1. The National Vaccine Injury Compensation Program comprised Part 2 of the National Childhood Injury Act of 1986, 42 U.S.C. § 300aa-1 *et seq.* (West 1991), as amended by Title II of the Health Information, Health Promotion, and Vaccine Injury compensation Amendments of November 26, 1991 (105 Stat. 1102).

2. The Vaccine Injury Table, as amended in 1995, 1997 and 1998, provides that, in order to be accorded a rebuttable presumption of causation, the symptoms of a post-MMR vaccine encephalopathy must manifest itself "not less than 5 days and not more than 15 days" after immunization. 42 C.F.R. § 100.3(a).

3. Petitioners did not seek review of the special master's holding that petitioners have failed to present a prima facie case of significant aggravation, pursuant to 42 U.S.C. § 300aa-11(c)(1)(C)(i), and, thus, will not be reviewed by this court.